IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

LIFENET HEALTH, Plaintiff, v. LIFECELL CORPORATION, Defendant.	Civil Action No. 2:13cv486/HCM-DEM **DEFENDANT LIFECELL CORPORATION'S REPLY IN FURTHER SUPPORT OF ITS RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW UNDER FED. R. CIV. P. 50(b)**

Defendant submits this reply in further support of its renewed motion for judgment as a matter of law ("JMOL").

I. Defendant Does Not Directly Infringe Any Asserted Claim.

Plaintiff failed to present any evidence that Defendant has ever made, used, offered for sale, sold, or imported a plasticized soft tissue graft meeting the requirement that "one or more plasticizers are not removed from [an/said] internal matrix of said soft tissue graft prior to transplantation into a human."[1] The "not removed" limitation requires: (1) there be transplantation of the graft into a human because it is *impossible* to determine if the limitation is met until transplantation occurs, and (2) inquiry into how the grafts have been prepared for transplantation to determine whether any plasticizer is removed before the procedure. *See* Pre-Trial Conf. Tr. (D.I. 293) at 3:11-15; D.I. 298 at 11. Plaintiff's infringement case fails for the simple reason that Defendant undisputedly does not prepare grafts for transplantation or transplant grafts into humans. When Defendant makes or sells the accused products, there exists

[1] As explained in Defendant's opening brief (D.I. 420) at 14-16, Plaintiff also failed to offer legally sufficient evidence that other claim limitations are met.

no apparatus meeting the "not removed … prior to transplantation" limitation, nor has any method been performed that includes that requirement. Defendant's manufacture and sale of the accused grafts (the basis for Plaintiff's infringement claim, *see* D.I. 432 at 8 n.4), thus cannot itself be an act of direct infringement

Plaintiff presents two arguments for why the Court should excuse its failure to provide evidence to support a direct infringement case: (1) Defendant waived the argument that Plaintiff failed to satisfy its burden of proof on direct infringement (which Plaintiff terms a "divided infringement" defense), and (2) the "not removed … prior to transplantation" limitation should be read out of the claims. Those arguments lack merit and should be rejected.

A. Defendant Did Not Waive Its Defense Of No Direct Infringement.

Plaintiff makes the meritless assertion that Defendant waived what Plaintiff calls a "divided infringement" argument. In reality, Plaintiff is attacking a basic defense that Defendant has argued consistently throughout this case: that Defendant does not directly infringe any claim because it does not engage in conduct that meets each and every requirement of an asserted apparatus or method claim. Defendant's defense that its conduct does not directly infringe is not new. Indeed, it was identified by *both* sides in the pre-trial order as an issue to be tried. *See, e.g.*, D.I. 296 at 22-23. Plaintiff expressly recognized an issue for trial was "Whether LifeCell infringes directly claims 1, 2, 3, 4, 7, 8, and 10 of the '200 patent by making, using, selling or offering for sale in the United States LifeCell's Accused Products." *Id.* at 22.

Defendant has consistently maintained its position that the accused products as made and sold do not meet the "not removed … prior to transplantation" limitation, and that whether the limitation is met needs to be evaluated at the time of transplantation and depends on actions of surgeons (or others) in the operating room. *See, e.g.*, D.I. 62 at 18-19; D.I. 195 at 5-7; D.I. 210 at 9; D.I. 269; D.I. 271. There is absolutely nothing new about this.

Moreover, the fact that infringement of the asserted claims would depend on the actions of third parties was squarely raised as early as *Markman* proceedings. In Defendant's opening *Markman* brief, for example, Defendant explained that a problem with the "not removed … prior to transplantation" limitation is that "it is not possible to determine whether any particular product will be used in an infringing manner, ***as infringement will depend on whether or not a surgeon (or some other person in the operating room) takes the steps of removing the plasticizers prior to transplanting the product***." D.I. 62 at 18-19 (emphasis added). This issue was also briefed on summary judgment and discussed during the Pre-Trial Conference. D.I. 195 at 5-7; D.I. 210 at 9; Pre-Trial Conf. Tr. at 3:2-15, 18:6-19:10, 56:15-17, 61:18-63:11. The Court recognized in its Order on motions in limine that actions of surgeons (their two-minute rinse of accused grafts) are relevant to alleged infringement because of the claim language. D.I. 324 at 6.

Plaintiff also misstates the record in asserting Defendant did not raise an issue of "divided infringement" prior to the close of evidence. D.I. 432 at 3-4. Defendant specifically discussed "divided infringement" in a Rule 50(a) motion, which the Court stated was deemed submitted at the end of phase three of the trial (which had four phases in total). Tr. at 1589:13-24, 1594:10-1595:15; D.I. 363-1 at 4-6. Defendant also requested a jury instruction on the issue, D.I. 361 at 9-10, and raised the issue again during the charge conference, Tr. at 1639:25-1640:20.

Thus, Plaintiff cannot reasonably contend it lacked notice of Defendant's defense that there is no direct infringement because Defendant's actions in making, using, offering for sale, or selling the accused grafts do not meet each and every requirement of any asserted claim.[2]

[2] Plaintiff's citation to *Summit 6 LLC v. Research in Motion Corp.*, No. 3:11-cv-367-O, 2013 U.S. Dist. LEXIS 95164 (N.D. Tex. June 26, 2013) is entirely misplaced. There, the "divided infringement" issue the court declined to address was raised by the defendant for the first time in its post-trial JMOL reply brief, and the plaintiff had no opportunity to respond. *Id.* at *14 n.6. If anything, *Summit 6* supports Defendant's noninfringement position. The court agreed there was (continued…)

Defendant consistently maintained the defense throughout the litigation. Plaintiff even addressed it in prior briefing. *See* D.I. 62 at 18-19; D.I. 195 at 5-7; D.I. 210 at 9; D.I. 269; D.I. 271. There plainly was no waiver.

Finally, contrary to Plaintiff's assertion, there is no inconsistency between Defendant's showing that the pre-implantation saline soak of the accused grafts removes plasticizer from the internal matrix, and the argument that even if there were no removal, *Defendant itself* does not make or sell an apparatus or process meeting all of the requirements of the claims. D.I. 432 at 3. These are two independent reasons why Defendant is entitled to JMOL of no infringement. First, Plaintiff failed to prove that there is ever an apparatus or method that meets the claim requirement of being transplanted where there is no removal of plasticizer from the internal matrix prior to the transplantation. Second, even were there evidence that such an apparatus had been created (and there is not), the evidence indisputably shows Defendant does not itself transplant the accused products, and Plaintiff has failed to prove that *Defendant itself* made or sold any apparatus or method that, as made or sold, meets the "not removed" requirement of the claims.[3] As Defendant has consistently explained, in summary judgment briefing and its Rule 50 motions, this case is analogous to *Cross Med. Prods.*, 424 F.3d 1293, 1311 (Fed. Cir. 2005) in that the grafts made and sold by Defendant do not meet all of the requirements of the claims and thus cannot directly infringe.

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inadequate evidence of direct infringement, explaining that while the record evidence could "be used to show direct infringement by customers, it does not show that [the defendants] directly infringed." *Id.* at *16. Unlike here, the plaintiff there also alleged indirect infringement.

[3] Plaintiff wrongly implies Defendant could be a direct infringer because it conducted testing to determine the amount of plasticizer removed from the internal matrix by a saline soak. D.I. 432 at 2. The testing did not involve transplantation into humans and would not meet the requirement of no removal "prior to transplantation into a human." Also, Defendant's testing shows plasticizers are removed from the internal matrix in a two-minute saline soak.

B. Defendant Does Not Directly Infringe Any Asserted Apparatus Claim.

Lacking evidence that the grafts as made or sold by Defendant meet the "not removed … prior to transplantation" limitation, Plaintiff attempts to argue that the limitation is not "an independent claim element," but rather "a characteristic of the plasticized soft tissue graft." D.I. 432 at 1. This is clearly wrong. "All the limitations of a claim must be considered meaningful," *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991), and "an accused product or process is not infringing unless it contains each limitation of the claim," *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005). Plaintiff cannot overcome its failure of proof as to the "not removed … prior to transplantation" limitation by contending the claim language does not pose any independent limitation on the claim.

Moreover, Plaintiff's attempt to read the limitation out of the claim by characterizing it as a "characteristic" or "property" is incompatible with the claim language, claim construction, and intrinsic evidence. Such an argument has also previously been rejected. *See Markman* Tr. (D.I. 120) at 69:1-8; D.I. 123 at 10-11.[4] The "not removed" limitation was added to narrow the claims, to overcome a rejection of the original claims as anticipated by Cavallaro. Plaintiff represented to the PTO that this limitation distinguished Cavallaro. DTX 463 at FH_1132-33. If it were simply a "characteristic" of a plasticized soft tissue graft, however, it could not have distinguished Cavallaro. *See PAR Pharm., Inc. v. TWI Pharms., Inc.*, 2014 WL 6782649, at *7 (Fed. Cir. Dec. 3, 2014) (if a limitation is not an additional requirement but rather a characteristic necessarily present in the claimed invention, it "adds nothing of patentable consequence").

[4] Plaintiff similarly argued during the pre-trial conference that it should be allowed to argue that the "not removed" claim limitation is met if plasticizer is not removed prior to packaging. The Court rejected that argument in light of the clear requirements of the "not removed . . . prior to transplantation" limitation. *See* Pre-Trial Conf. Tr. (D.I. 293) at 3:11-15.

The record evidence demonstrates that, as in *Cross Med. Prods.*, 424 F.3d at 1311, the products Defendants made and sold do not meet all requirements of the claimed apparatuses and thus cannot directly infringe. The "not removed … prior to transplantation" requirement of the claimed apparatuses cannot exist unless and until a graft is transplanted into a human, and plainly this requirement is not present in the accused grafts as sold. Further, Plaintiff does not dispute that there is no evidence Defendant transplanted any accused product into a human, and consequently Defendant itself cannot possibly have made the claimed apparatuses. Thus, JMOL of no infringement should be entered on claims 1-4.

C. Defendant Does Not Directly Infringe Any Of The Asserted Method Claims.

Plaintiff's opposition likewise confirms the absence of evidence that Defendant practices each and every limitation of the asserted method claims, as would be required for Defendant to directly infringe them. As with the apparatus claims, Plaintiff attempts to sidestep its failure of proof by reading the "not removed … prior to transplantation" limitation out of the claims. Plaintiff makes the remarkable argument that the method of independent claim 7 requires *only* the step of "impregnating," and the "not removed" limitation is merely "a condition resulting from the impregnating step," which would mean it does not further limit the claims and is superfluous. D.I. 432 at 9. That is incorrect. Plaintiff may not rewrite the claims to defeat a JMOL motion. Further, for the reasons discussed above, Plaintiff's position is contrary to the claim language and construction as well as the intrinsic evidence.

Plaintiff also mischaracterizes the claims in asserting that Defendant, by identifying the failure of proof that Defendant practices the "not removed … prior to transplantation" limitation, "creates" additional steps not found in claims 7, 8, and 10. D.I. 432 at 8. Each of these claims expressly requires a method comprising (1) "impregnating a cleaned, soft tissue graft with one or more plasticizers to produce a plasticized soft tissue graft," as well as (2) "and said one or more

plasticizers are not removed from an internal matrix of said plasticized soft tissue graft prior to transplantation into a human." Contrary to Plaintiff's argument, the final limitation must be given effect and may not be disregarded. As explained above, it requires transplantation and inquiry into how the graft was prepared for the transplant to determine whether plasticizer was removed. Defendant does not "create" those requirements; rather, the limitation demands them.

Here, the record evidence establishes that *Defendant* does not perform the "not removed … prior to transplantation" limitation of the claims. A direct infringement allegation against a party that does not perform all steps of the method must fail as a matter of law. *See, e.g.*, *Mirror Worlds, LLC v. Apple Inc.*, 692 F.3d 1351, 1359-60 (Fed. Cir. 2012) (no direct infringement because patentee failed to establish the defendant itself performed all steps of the claimed method). Therefore, Defendant cannot directly infringe.

Finally, Plaintiff argues that "nothing in that claim language refers to any affirmative step, such as actual transplantation or graft preparation, which would require any action by a third party." D.I. 432 at 8. But that is incorrect. The claims by their terms require a step of transplantation, PTX 1 at 24:38-50, 24:53-55; D.I. 298 at 11, which is necessary to determine whether there has been removal of plasticizer prior to the transplantation.[5] The claims imply, and the '200 patent clearly teaches, that transplantation into a human is performed by surgical staff (*i.e.*, surgeons and their assistants). *See, e.g.*, PTX 1 at 12:27-34. Therefore, by requiring no removal "prior to transplantation into a human," the claims convey that actions of surgical personnel are necessary to the claimed method.

[5] Contrary to Plaintiff's assertion, the mere fact that the claims require that plasticized soft tissue grafts be "suitable for transplantation" does not negate the separate requirement that plasticizers are "not removed … prior to transplantation into a human."

Because there is no legally sufficient evidence that Defendant practices the "not removed … prior to transplantation" limitation of the asserted method claims, JMOL should be granted that Defendant does not directly infringe those claims.

D. Under The Proper Construction Of "Not Removed . . . Prior To Transplantation," The Evidence Is Legally Insufficient To Support A Finding That Defendant Infringed The Asserted Claims.

As Defendant discussed in its opening brief, the parties had fundamental disputes as to the "plain meaning" of the "not removed … prior to transplantation" term and the scope of the claims. Although the Court had provided clarifications to the parties, it did not provide corresponding guidance to the jury to allow the jury to apply the proper meaning of the term, despite Defendant's requests. Plaintiff is also wrong to suggest there was no dispute regarding the scope of this term at trial. In fact, Plaintiff advanced an interpretation inconsistent with the Court's claim construction order, suggesting the limitation permitted anything short of complete removal of plasticizer and that removal was permissible as long it occurred after manufacture or packaging. *See, e.g.*, Tr. at 1652:22-1653:12; 1656:25-1657:8; 1742:5-10, 1778:22-25. By instructing the jury that the term required no further construction and declining to provide Defendant's requested clarification, the Court failed to instruct the jury properly regarding the meaning of a key disputed claim term, to the prejudice of Defendant.

Plaintiff distracts from this issue by dwelling on a statement in Defendant's opening brief that the correct interpretation of the "not removed" term "would require that there is no partial or full removal of the plasticizers from the internal matrix prior to transplantation." This is not a new construction, nor was it offered as such. Defendant is merely restating its consistent position that, contrary to Plaintiff's arguments, the claims do not permit removal of *any* plasticizer (i.e., partial removal). Throughout the case, Defendant has maintained that a legally correct definition of the term requires that "no plasticizers are removed prior to transplantation."

D.I. 123; *see* D.I. 62 at 14-16 (Defendant's proposed construction: "no processing steps are taken, before transplantation into a human, that result in any amount of the one or more plasticizers being taken out of the internal matrix of the plasticized soft tissue graft.").

Under a correct claim construction of "not removed … prior to transplantation," there is no legally sufficient evidence of infringement. The record evidence indisputably shows that (1) the accused grafts are decellularized grafts, and (2) plasticizer is removed from the decellularized tissue matrices—i.e., the internal matrix—prior to transplantation when they are soaked in saline in the operating room. *See* Def's Opening Br. (D.I. 420) at 10.

Plaintiff's assertions that plasticizer is not removed from the internal matrix lack merit. *First*, the record evidence establishes that decellularized tissue is "extracellular matrix," which is also synonymous with "internal matrix." *See* DTX 183; Tr. at 220:16-20 (Qin); 486:1-11, 510:5-8 (Kaplan); 785:10-18 (Harper); 934:1-16 (Dahlgren); 1012:16-1014:12 (Badylak). Unrebutted evidence shows there is removal of plasticizers from the decellularized tissue (the extracellular matrix), which necessarily means there is removal of plasticizer from the internal matrix.

Second, it was *Plaintiff* that bore the burden to prove a negative—that plasticizer is "not removed"—but Plaintiff offered no evidence that could demonstrate this. Plaintiff proffered no testing, modeling, calculation, or other evidence to show that of the plasticizer indisputably removed from the accused grafts in a saline soak, *none* is removed from the internal matrix. Plaintiff points to testimony about mechanical characteristics of accused grafts after a soak, but Plaintiff's own expert conceded that he could not say that removal of, for example, 5% of the loosely bound plasticizer from the internal matrix would significantly impact the mechanical properties of the graft. *See* Tr. at 586:25-587:3 (Kaplan); *see also* 587:3-6 (Kaplan) (stating merely that "you can't remove *the majority* of the material even after an extended wash")

(emphasis added). Thus, the mechanical properties of a graft after a saline soak provide no basis to conclude that *no* plasticizer was removed from the internal matrix, as the claims require. Rather, Plaintiff failed to present any legally sufficient evidence to support its contention that none of the plasticizer that is removed from Defendant's decellularized tissue matrices in a saline soak is removed from the internal matrix of the graft.[6]

Lacking evidence to meet its burden, Plaintiff resorts to the erroneous assertion that the "not removed … prior to transplantation" limitation must be satisfied because plasticizer ***cannot*** be removed from the internal matrix. Plaintiff asserts, for example, that "plasticizers cannot be removed from the internal matrix whether or not the grafts are rinsed," D.I. 432 at 5, and "there is nothing that surgeons can do that affects the presence of plasticizer in the internal matrix prior to transplantation," *id.* at 9-10.[7] Thus, rather than demonstrating the accused grafts meet the limitation, Plaintiff attempts to eliminate the limitation by contending it is impossible to remove plasticizer from the internal matrix. However, the claim language cannot bear Plaintiff's interpretation, which is contradicted by Plaintiff's own representations to the Patent Office that this limitation narrowed the claims to distinguish Cavallaro (DTX 463 at FH_0001132-33) as well as the disclosures of the '200 patent, *see, e.g.*, PTX 1 at 12:14-16; *id.* at 4:49-51 ("It is a

[6] Plaintiff cites the Court's statement that the limitation could be met if "plasticizer does not come from the internal matrix, but rather comes from the exterior of the graft." D.I. 432 at 5. Plaintiff's own expert, however, conceded that in a two-minute soak in saline, plasticizer does not merely come from the exterior, but comes out from the interior of the graft. Tr. at 577:14-19, 578:1-3 (Kaplan); *see also* Wolfinbarger Dep. at 97:15-18, 97:20-98:09, 98:11-24, 99:2-3.

[7] *See also id.* at 6 ("[T]here is nothing that surgeons can do, after they receive the graft made and sold by LifeCell that affects the content of plasticizer within the internal matrix prior to transplantation."); *id.* at 9 ("The language that follows in the claim – 'said one or more plasticizers are not removed from an internal matrix of said plasticized soft tissue graft prior to transplantation in to a human' – is not a step, but rather a condition resulting from the impregnating step.").

further objective of the present invention to provide plasticized bone and soft tissue products where the plasticizer can be readily removed prior to implantation.").

Third, Plaintiff's theory rests on a specialized construction of "removed from the internal matrix" that its expert improperly offered at trial and that deviated from the agreed-upon construction of "internal matrix." Plaintiff admits that its expert offered what it calls "an explanation as to how one of skill in the art would understand the claim construction in view of the disclosure in the '200 patent and his or her knowledge of the chemical interactions with the matrix components." D.I. 432 at 13-14. This is precisely the exercise of claim construction, and it was inappropriate for Plaintiff's expert to offer a new construction of claim terms to the jury.

In particular, to avoid a finding of no infringement in the face of test data showing removal of plasticizer from the accused grafts in a saline soak, Plaintiff advanced an argument that so-called "free" plasticizer (which Plaintiff asserted replaced "free" water) is not contained "in" the internal matrix and thus "free" plasticizer that comes out in a soak is not "removed from the internal matrix." The premise, that so-called "free" plasticizer is not "in" the internal matrix, is plainly incorrect, D.I. 342 at 14-15, as it is contrary to the '200 patent's disclosures. Indeed, Plaintiff itself explained in *Markman* proceedings that "free" water is in the internal matrix. D.I. 65 at 20. Plaintiff proposed, for example, that the term "impregnated" means "wherein the internal matrix is filled such that space occupied by ***free*** and bound ***water in the internal matrix*** is replaced sufficiently to plasticize the tissue graft." *Id.* (emphasis added). Thus, Plaintiff recognized that "free" water (and by extension "free" plasticizer that replaces it) quite clearly is, according to the terms of the '200 patent and the parties' agreed-upon definition of "internal matrix," *in* the internal matrix. The Court's claim construction likewise defines a "plasticized soft tissue graft" as "a load-bearing and/or non-load-bearing soft tissue product … composed of

an internal matrix where free and loosely bound waters of hydration in the tissue have been replaced with one or more plasticizers." D.I. 123 at 14 (emphasis added). Here too, "free" water is by definition *in* the "internal matrix," and thus so is so-called "free" plasticizer that replaces it.

Thus, under a proper construction, "free" plasticizer is contained in the internal matrix, and the claims do not permit any removal of plasticizer, whether "free" or "loosely bound." As Plaintiff's expert admitted, "free" plasticizer is removed from the accused products by a saline rinse. Tr. at 515:11-15. Because undisputed evidence thus shows that "free" plasticizer is "removed from the internal matrix," JMOL of no infringement should be granted.

E. The Record Evidence Is Legally Insufficient To Support A Finding That Defendant's Products And Processes Meet Other Elements Of The Claims.

As explained in Defendant's opening brief, additional claim elements are also missing from the accused products: (1) "plasticized soft tissue graft"; (2) "transplantation into a human"; (3) "without rehydration"; (4) "impregnating" and "impregnated"; and (5) "incubating." Plaintiff fails to identify legally sufficient evidence to demonstrate the presence of these elements.

II. The Asserted Claims Are Invalid.

A. Apparatus Claims 1-4 Are Indefinite Because They Impermissibly Recite An Apparatus And A Method For Using The Apparatus.

As Defendant explained in its opening brief, claims 1-4 are invalid as indefinite because they impermissibly combine a claim to an apparatus (a "plasticized soft tissue graft") with a limitation on how the apparatus is used ("plasticizers are not removed … prior to transplantation"). D.I. 420 at 16-17. The "not removed … prior to transplantation" limitation depends on the actions of users—surgeons and their assistants—thus making it unclear when infringement would occur. This is precisely the problem the Federal Circuit has identified with product claims that impose use limitations, and a reason why those claims are indefinite. *See, e.g.*, *H-W Tech., L.C. v. Overstock.com, Inc.*, 758 F.3d 1329, 1336 (Fed. Cir. 2014); *IPXL*

Holdings, L.L.C. v. Amazon.com, Inc., 430 F.3d 1377, 1384 (Fed. Cir. 2005).

To contest indefiniteness, Plaintiff rests on its faulty argument that the "not removed . . . prior to transplantation" limitation is a "physical characteristic or functional aspect of the plasticized soft tissue graft." D.I. 432 at 17. The claim language, however, is clearly to the contrary, as it requires transplantation of a plasticized soft tissue graft into a human, and imposes restrictions on what actions a surgeon may take on a "plasticized soft tissue graft" prior to transplanting it; the claim does not merely describe a characteristic of plasticized soft tissue grafts.[8] As the Court has stated, "the accused graft is one where plasticizers are not removed prior to transplantation; the final act is transplantation, and the graft can only infringe upon the patent if there is no removal of plasticizers." D.I. 298 at 11; *see also* Markman Tr. at 68:15-23; Pre-Trial Hearing Tr. (D.I. 293) at 18:6-19. The '200 patent's specification reinforces that removal of plasticizer depends on actions taken with respect to the plasticized soft tissue graft, including in the operating room, by users. *See, e.g.*, PTX 1 at 11:54-12:19. The specification explicitly describes actions that remove plasticizer (such as soaking in saline) as "further *processing* of grafts." *Id.* at 12:16-17 (emphasis added).

Thus, the "not removed … prior to transplantation" limitation constitutes a method of use limitation on apparatus claims 1-4, which renders the claims invalid as indefinite.

B. The Asserted Claims Were Anticipated By Werner And Duran.

Plaintiff's opposition brief confirms that JMOL should be granted that the asserted claims were anticipated by the Werner (DTX 633) and Duran (DTX 631) prior art references.

1. Werner Anticipated the Asserted Claims.

[8] Nor does it state functional requirements of the environment in which the product is used, as was the case in *HTC Corp. v. IPCom GmbH & Co.*, 667 F.3d 1270, 1277 (Fed. Cir. 2012).

Plaintiff does not contest Werner disclosed all elements of the asserted claims besides (a) "cleaned" and (b) "plasticized soft tissue graft." Further, Plaintiff fails to identify any evidence from which a reasonable jury could conclude that Werner did not disclose these limitations.

To argue Werner does not disclose a "cleaned" tissue, Plaintiff fails to apply the Court's claim construction. It is well-established, however, that a patentee cannot avoid a finding of anticipation by trying to distinguish prior art based on a requirement not found in the claims, as construed. *See, e.g.*, *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 976-77 (Fed. Cir. 2010). "Cleaned" was construed as "a process during which cellular elements and small molecular weight solutes are removed." D.I. 123 at 9. Unrebutted evidence—including admissions of Plaintiff's expert—establish that Werner disclosed such a process. *See* D.I. 420 at 18-19 (citing, *e.g.*, Tr. at 1522:5-25, 1562:6-10). Plaintiff admits that using the Werner process "some of the cell components, the lipids, the grease materials, will be removed." D.I. 432 at 18 (citing Tr. at 1522:22-23 (Kaplan)). Plaintiff's only argument that Werner did not disclose a "cleaned" tissue rests on requirements not found in the construction,[9] including that a graft not be a "potential source[] of the transmission of mad cow disease." D.I. 432 at 18.[10]

Plaintiff's opposition also demonstrates the lack of evidence to permit any conclusion other than that Werner disclosed a "plasticized soft tissue graft." Werner disclosed the same

[9] Plaintiff also misstates the testimony of Defendant's expert. D.I. 432 at 18. He did not testify that "the scleroproteins disclosed in Werner are potential sources of the transmission of mad cow disease," *see* Tr. at 1364:18-23, nor did Plaintiff's expert. Indeed, he was asked only about the "Lyodura" product, which is quite clearly *not* the cleaned tissue of Werner, but mentioned only in the introductory section of Werner as an example of a prior art tissue. DTX 633 at 1:27-29.

[10] Plaintiff also claims the Court intended to construe "cleaned" to require "'virtually all' cellular elements are removed," D.I. 432 at 18 n.11, but that is not the Court's construction. The Court was merely quoting a passage of the '200 specification discussing one possible method of cleaning, *see* D.I. 298 at 22 & Ex. 1 at 11. Indeed, the soft tissue examples in the '200 patent, PTX 1 at 22:32-24:2, are cleaned with "Allowash," which Plaintiff's employee testified was "[a]bsolutely not" a "decellularizing technology," Tr. at 415:1-3 (Brame).

process to plasticize soft tissue as the examples of the '200 patent (soaking the tissue in a solution of 30% glycerol), which according to the '200 patent would inherently yield a "plasticized soft tissue graft." To contest this limitation, Plaintiff points to its expert's direct testimony regarding data in Werner on tensile strength at various time points. But Plaintiff disregards its expert's further testimony admitting that Werner's statement regarding an increase in tensile strength by a "factor of 1.7 to 7.0" concerned the strength of tissue removed from test animals many days *after* implantation, not strength of the grafts at the time of implantation (which is the relevant time). Tr. at 1547:2-14, 1548:13-25. And, Plaintiff's expert admitted that at the time of implantation, there was *no statistically significant difference* in tensile strength, Tr. at 1552:1-8 (Kaplan). Thus, to the extent the strength comparisons have any relevance, its expert's admission shows the data further demonstrate that Werner disclosed a "plasticized soft tissue graft." Plaintiff's attempts to evade this admission by referencing Werner's title and statements about "increasing the biological stability" also lack merit. D.I. 432 at 19 n.12. Nothing about a "plasticized soft tissue graft" precludes it from having increased stability or integrity. These statements could not support a conclusion that Werner was not "plasticized."

2. Duran Anticipated the Asserted Claims.

Plaintiff's argument that Duran was not "cleaned" fails for the same reason as its argument with respect to Werner. Plaintiff's expert conceded on cross-examination that Duran discloses cleaning soft tissue with acetone, which would "extract some of the cell membrane material" from the soft tissue graft. Tr. at 1570:8-14.

Plaintiff also argues that Duran does not disclose a "plasticized soft tissue graft" because of "the presence of heparin in Duran." D.I. 432 at 20. However, as Defendant explained, D.I. 420 at 21, the '200 patent discloses that a 30% glycerol solution will plasticize a soft tissue whose internal matrix contains "polysaccharides." PTX 1 at 3:7-12, 22:50-23:5, 23:46-58. The

conclusory assertion of Plaintiff's expert that the presence of heparin might prevent even a 30% or 50% glycerol solution from replacing *any* free or loosely bound waters of hydration in the tissue, based solely "on [heparin's] chemistry as a polysaccharide," Tr. at 1533:8-16, is thus flatly contrary to the disclosure of the '200 patent, and cannot support a finding of no anticipation. Moreover, Plaintiff's argument as to mechanical properties, D.I. 432 at 20, is contradicted by the admission of Plaintiff's own expert that "the mechanical properties [of Duran's graft] are similar to natural hydrated tissue," Tr. at 1568:18-1569:2.

Finally, Plaintiff's brief lays bare the lack of legally sufficient evidence to allow Plaintiff to antedate Duran by showing earlier conception and diligence in reduction to practice. Plaintiff bore the burden to offer evidence of conception before Duran and diligence in reduction to practice. Tellingly, Plaintiff's only citations to the trial record consist exclusively of attorney argument, which is not evidence. The only other material Plaintiff cites—documents identified as PTX 177, PTX 180, and PTX 182—were *not admitted* into evidence at trial (and were not even offered). The record establishes that Duran is prior art to the '200 patent, and no reasonable jury could conclude that Duran did not anticipate the asserted claims.

C. The Asserted Claims Were Obvious In Light Of The Prior Art.

JMOL of obviousness should also be granted. Apart from repeating its flawed argument that neither Werner nor Duran disclosed a "cleaned," "plasticized soft tissue graft," which is wrong for the reasons discussed above, Plaintiff misstates the record in asserting that Defendant "adduced no evidence" of "a motivation to combine the cited references and a reasonable expectation of success." D.I. 432 at 21. Considerable testimony, including admissions of its own expert, explains (1) why a POSA would have been motivated to combine Werner or Duran with the Livesey or Goldstein patents or with a POSA's undisputed knowledge of cleaning (to "rid the tissue of . . . those molecules that cause the recipient to reject it"), and (2) that a POSA

would have had a reasonable expectation of success in doing so. Tr. at 1569:7-13 (Kaplan); 1284:5-1285:5, 1288:10-20, 1292:23-1294:15 (Badylak).

Plaintiff's attempt to identify evidence of secondary considerations also fails. The evidence Plaintiff cites does not establish the existence of any such considerations, and the record is clear that Plaintiff did not offer evidence of any. All Plaintiff's cited evidence, besides that on supposed "failure of others," is from phases one or two of the trial, and thus was not offered as evidence of secondary considerations.[11] In fact, the Court informed Defendant during "phase two" of the trial that "it would not be appropriate at this point" for Defendant to present evidence rebutting any potential secondary considerations, because Plaintiff had not yet "put[] on secondary considerations of nonobviousness." Tr. at 1300:15-1301:20. Plaintiff's counsel expressly agreed that secondary considerations, such as commercial success, would only "come up in a later phase," phase three. Tr. at 1304:16-20. During phase three, Plaintiff made the decision not to present any evidence of secondary considerations (and thus Defendant did not present rebuttal on this issue in phase four). Having made that choice, Plaintiff cannot now assert that evidence it offered in phase one or phase two establishes secondary considerations.

An additional, and fundamental, failing in Plaintiff's assertion of secondary considerations is the complete lack of testimony establishing a "nexus" to the claims. "Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006). Tellingly, everything Plaintiff cites as support for a nexus is from Plaintiff's infringement and damages case in phase one of the trial, and did not

[11] The cited evidence does not show failure of others. Plaintiff cites its expert's testimony that certain references did not invalidate the claims. *See* D.I. 432 at 23. But Plaintiff offered no evidence that other persons tried and failed to solve the problem of the claimed invention.

make the necessary comparison of the claims to the asserted prior art. *See In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (nexus requires showing that secondary consideration resulted from a feature in the claimed invention not found in the prior art). Plaintiff has not cited any testimony of its expert explaining an alleged nexus because there is none.

D. The Asserted Claims Were Not Enabled To Their Full Scope.

Plaintiff concedes that if a POSA would have needed to engage in an "unduly extensive" amount of experimentation to practice the full scope of the asserted claims, they are invalid for lack of enablement. D.I. 432 at 25. In the *Cephalon, Inc. v. Watson Pharms, Inc.* case cited by Plaintiff, for instance, "experimentation was unreasonable" when 1 1/2 to 2 man-years of effort would be required to practice the patented invention. 707 F.3d 1330, 1337 (Fed. Cir. 2013). The unrebutted evidence here establishes as a matter of law that the experimentation necessary to practice the full scope of the claims, which far exceeds that in *Cephalon*, would be undue.

Plaintiff does not dispute that the asserted claims cover use of a large number of different chemicals, and a huge number of combinations of these chemicals, to make "plasticized soft tissue grafts"; that the '200 patent provides no examples of "plasticized soft tissue grafts" using any chemical other than glycerol; that the '200 patent provides no guidance or direction for the experimentation; and that the inventors themselves had not made such grafts.

In the face of the massive and unguided experimentation that would be necessary to practice the full scope of the claims, Plaintiff argues that according to its expert, testing would be "simple" and would take "about two weeks." D.I. 432 at 25. Plaintiff ignores, however, that its expert admitted the "two weeks" of "prescreening" per chemical does not constitute all of the testing that would be necessary to practice *the claims* (the relevant issue for enablement). The claims require that a plasticized soft tissue graft be suitable for transplantation into a human, and Dr. Kaplan admitted that testing for such suitability would be far more complex and require—for

each separate material—that the two weeks of "prescreening" be followed by "in vivo testing" in animals that "would take months." Tr. at 1586:21-25, 1587:6-1588:4. Dr. Kaplan admitted that such testing would need to be repeated for each different potential plasticizer (the specification provides a non-exclusive list of 18 examples), each combination, and each type of soft tissue (the specification provides a non-exclusive list of 6 examples). *See, e.g.*, *id.* at 1587:11-20. At a minimum, practicing the full scope of the claims would require years of testing without the benefit of any guidance from the specification, which is undue experimentation. Indeed, there is nothing to suggest that all of the listed chemicals would even work.

Plaintiff sought broad claim language "at the peril of losing any claim that cannot be enabled across its full scope of coverage," *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012). As the record evidence shows, it obtained claims that a POSA could not make and use to their full scope without undue experimentation. The Court should therefore grant JMOL that the claims are invalid for lack of enablement.

E. There Is No Legally Sufficient Evidence To Support The Damages Award.

Plaintiff's arguments regarding damages are nearly identical to its opposition to LifeCell's Rule 59 motion for a new trial, or remittitur, on damages issues and fail for the same reasons. *First*, the Entire Market Value Rule (EMVR) is not limited to "multi-component" products. *See* Defendant's Rule 59 Reply Br. at 11-12. Moreover, neither Mr. Gallagher nor any other witness provided sufficient evidence that the requirements of the narrow EMVR exception were met. On the contrary, extensive unrebutted evidence shows that numerous features influence demand. *See id.*at 13-15. *Second*, Plaintiff is incorrect that Mr. Gallagher relied on more than the initial offer of 5% to Edwards in determining his proposed royalty rate. *See id.* at 15-16. Moreover, he did not tie any other evidence to his proposed 5% rate or explain how it affected his proposal. Basing his proposed royalty rate on this single, unrequited license offer is

insufficient to support the jury's verdict. *See id.* at 15-17.

F. Plaintiff Failed To Prove That It Provided Constructive Notice.

As Plaintiff acknowledges, "[t]o satisfy the marking requirement, a patentee must consistently mark substantially all of its products and no longer distribute unmarked products." D.I. 432 at 30 (*citing Aero Prods. Int'l, Inc. v. Intex Recreation Corp.*, No. 02 C 2590, 2004 WL 5129997, at *2 (N.D. Ill. Dec. 15, 2004)). Plaintiff, however, clearly failed to prove that it complied with the marking requirement at the relevant time, which is the period beginning when Plaintiff began selling its DermACELL, OraCELL, and ArthroFLEX products in 2010 and ending when Plaintiff filed its complaint in September 2013. Plaintiff has identified no evidence of pre-suit compliance with the marking requirement, effectively conceding there is none. Plaintiff focuses on the adequacy of its *current* marking practices, but they are inapposite because there is no evidence establishing when they were implemented or that they were in place for the entire period its products have been on the market. *Cf. Am. Med. Sys., Inc. v. Med. Eng'g Corp.*, 6 F.3d 1523, 1537 (Fed. Cir. 1993) ("[O]nce marking has begun, it must be substantially consistent and continuous in order for the party to avail itself of the constructive notice provisions of the statute."). There is a lack of legally sufficient evidence that Plaintiff complied with the marking requirement in the pre-suit period, and JMOL should be granted on this issue.

CONCLUSION

For the foregoing reasons and those set forth in Defendant's opening memorandum, Defendant requests entry of judgment as a matter of law in its favor.

Dated: January 8, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 8, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

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